


# Schedule of Accreditation

issued by

## United Kingdom Accreditation Service

2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

 <p><b>UKAS</b> MEDICAL 8659</p> <p>Accredited to <b>ISO 15189:2022</b></p>	<p><b>Imperial College Healthcare NHS Trust</b> <b>Operating as North West London Pathology</b></p> <p>Issue No: 025    Issue date: 25 March 2025</p>	
	<p>Department of Infection &amp; Immunity Sciences (Microbiology, I&amp;I and H&amp;I laboratories) Acrow East St Mary's Hospital Praed Street London W2 1NY</p>	<p>Contact: Nicola Mandikate Tel: +44 (0)20 331 15175 E-Mail: <a href="mailto:ICHC-TR.Pathologyqueries@nhs.net">ICHC-TR.Pathologyqueries@nhs.net</a></p>
<p><b>Testing performed by the Organisation at the locations specified below</b></p>		

### Locations covered by the organisation and their relevant activities

#### Laboratory locations:

Location details	Activity	Location code
<p><b>Address:</b> Microbiology Laboratory Charing Cross Hospital Fulham Palace Road London W6 8RF</p> <p><b>Local contact:</b> Nicola Mandikate Yvonne Iroadumba</p>	Microbiology	CXH (M)
<p><b>Address</b> Infection &amp; Immunity Laboratory 9<sup>th</sup> Floor Laboratory Block Charing Cross Hospital Fulham Palace Road London W6 8RF</p> <p><b>Local contact</b> Nicola Mandikate Yvonne Iroadumba</p>	Immunology Microbiology Serology Molecular Virology	CXH (I)
<p><b>Address</b> Histocompatibility &amp; Immunogenetics Laboratory G Block Hammersmith Hospital Du Cane Road London W12 0HS</p> <p><b>Local contact</b> Nicola Mandikate Yvonne Iroadumba</p>	Histocompatibility & Immunogenetics	HH



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**Site activities performed away from the locations listed above:**

Location details	Activity	Location code
FELIX Laboratory Ground floor Charing Cross Hospital Fulham Palace Road London W6 8RF  <b>Local contact:</b> Nicola Mandikate	Molecular virology	CXH (F)
Charing Cross Hospital 5 <sup>th</sup> floor I&I Laboratory Fulham Palace Road London W6 8RF  <b>Local contact:</b> Nicola Mandikate	Serology Immunology Virology	CXH (I5)
Charing Cross Hospital (hub) 4 <sup>th</sup> Floor Rapid Molecular laboratory Fulham Palace Road London W6 8RF  <b>Local contact:</b> Nicola Mandikate	Molecular Virology	CXH (Mol)
Specimen Reception (spoke) Hammersmith Hospital Du Cane Road London W12 0HS  <b>Local contact:</b> Nicola Mandikate	Molecular Virology	HH
Specimen Reception (spoke) St. Mary's Hospital Praed Street Paddington London W2 1NY  <b>Local contact:</b> Nicola Mandikate	Molecular Virology	SMH
Specimen Reception (spoke) Hillingdon Hospital Pield Heath Rd, Uxbridge UB8 3NN  <b>Local contact:</b> Nicola Mandikate	Molecular Virology	THH



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DETAIL OF ACCREDITATION

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code	
HUMAN BODY FLUIDS AND TISSUES	<u>Microbiology examination activities for the purpose of clinical diagnosis</u>	In House documented methods based on current Public Health England (PHE) Standards for Microbiology Investigations' (SMIs)	CXH (M)	
Blood,	General isolation for characterisation of microorganisms for the purpose of diagnosis	Manual or automated inoculation, incubation and image capture of culture media using SOPs		
Bone				
Bronchio-alveolar lavages (BAL) / washings, CPAP fluid				CSF SOP INIS-LP-204-X
Contact lens and fluid				Cross Infection SOP INIS-LP-201-X
Corneal scrape material				ENT SOP INIS-LP-270-H
CSF				Enteric C&S SOP INIS-LP-207-X
Drain fluid, dressings, bile				Faeces <i>C.difficile</i> culture SOP INIS-LP-203-X
Expressed breast milk				Female genital SOP INIS-LP-245-X
Faeces				GUM Bench SOP INIS-LP-246-X
Fluids, Aspirates, antral washouts				Fungal Culture SOP INIS-LP-256-X
Lymph node aspirates (including ultra sound guided EBUS)				H. pylori Culture SOP INIS-LP-209-X
Pleural effusions / fluid				Peritoneal Dialysis Fluid SOP INIS-LP-210-X
Prostheses, heart valves, Intra uterine devices				Sterile fluids SOP INIS-LP-211-X
Semen				Sterility Testing SOP INIS-LP-235-X
Sputum				Respiratory setup SOP INIS-LP-214-X
Swabs, pus				Respiratory read SOP INIS-LP-273-X
Tips and lines				Tissue and Bone SOP INIS-LP-212-X
Tissue, biopsies, brushes				Wounds & General Set Up Bench SOP INIS-LP-242-X
Urines, suprapubic aspirates, nephrostomy, ileal conduits, void bladder urines.				Wounds and General bench reading SOP INIS-LP-241-X
				Kiestra SOP INIS-LP-260-X



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<p>HUMAN BODY FLUIDS AND TISSUES (cont'd)</p> <p>Blood, body fluids, bone marrow harvests,</p> <p>Sputum Bronchio-alveolar lavages (BAL) / washings, Pleural fluid / effusions CSF, Fluids Early Morning Urine Gastric washings Lymph node aspirates (including ultra sound guided EBUS), Pus, Tissues, biopsies, brushes, skin biopsies, Blood, bone marrow</p> <p>Stem cells</p> <p>Swabs, Urine</p>	<p><u>Microbiology examination activities for the purpose of clinical diagnosis</u> (cont'd)</p> <p>Sterility for Human products</p> <p>Screening for Methicillin resistant <i>Staphylococcus aureus</i> (MRSA)</p>	<p>In House documented methods based on current Public Health England (PHE) Standards for Microbiology Investigations (SMIs):</p> <p>Fluorescent detection of CO2 levels to detect microorganisms using BACTEC FX:</p> <p>Blood culture FX SOP INIS-LP-322-X INIS-LP-323-X INIS-LP-244-X</p> <p>TB SOP INIS-LP-213-X</p> <p>Fluorescent Detection of O2 levels to detect Mycobacteria using Mycobacteria Growth Indicator Tube (MGIT), manual culture using Kirschner liquid medium</p> <p>TB SOP INIS-LP-213-X</p> <p>Fluorescent detection of CO2 levels to detect microorganisms using BACTEC FX</p> <p>Stem Cell SOP INIS-LP-322-X INIS-LP-323-X INIS-LP-244-X</p> <p>Blood culture FX SOP INIS-LP-216-X</p> <p>Manual or automated inoculation, incubation and image capture of culture media using:</p> <p>Cross Infection SOP INIS-LP-201-X</p>	<p>CXH (M)</p>



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Microbiology examination activities for the purpose of clinical diagnosis</u> (cont'd)	In House documented methods based on current Public Health England (PHE) Standards for Microbiology Investigations (SMIs):	CXH (M)
Bacteria, Fungi	Antimicrobial susceptibility testing of clinically significant bacteria and fungi	Manual disc diffusion using the latest EUCAST methodology. Manual reading or automated digital imaging by Kiestra using:  MIC and EUCAST sensitivity testing SOP INIS-LP-224-X  Fungal Susceptibility Testing SOP INIS-LP-233-X using Micronaut system  Kiestra SOP INIS-LP-260-X	
Bacteria, Fungi	Antimicrobial susceptibility testing of clinically significant bacteria and fungi	Automated antimicrobial susceptibility testing using BD Phoenix SOP INIS-LP-275-X	
Urine	Semi-quantification of white blood cells, red blood cells, squamous epithelial cells, bacteria, yeast, casts, spermatozoa	Manual microscopy (unstained) or automated cell counting by digital imaging using Sedimax ConTrust:  Manual Urine SOP INIS-LP-230-X  Menarini Sedimax SOP INIS-LP-239-X	
CSF, peritoneal dialysis fluid, ascitic fluid, Prosthetic joint fluid	Quantification of white blood cells and red blood cells	Manual count:  CSF SOP INIS-LP-204-X  Peritoneal dialysis fluid SOP INIS-LP-210-X  Sterile fluids INIS-LP-211-X	
Cultured isolates	Automated identification of bacteria, yeasts	Identification using Bruker Matrix Assisted Laser Desorption Ionization Time-of-Flight (MALDI-TOF):  MALDI-TOF SOP INIS-LP-240-X	



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<p>HUMAN BODY FLUIDS AND TISSUES (cont'd)</p> <p>Cultured isolates</p> <p>Cultured isolates</p> <p>Culture positive liquid media</p>	<p><u>Microbiology examination activities for the purpose of clinical diagnosis</u> (cont'd)</p> <p>Identification of bacteria, yeasts and fungi</p> <p>Serological typing of <i>Salmonella</i> sp. PSO, PSH, Vi, <i>Shigella</i> sp., <i>E. coli</i> O157, <i>V. cholera</i> O1</p> <p>Identification of <i>M. tuberculosis</i> complex isolates</p>	<p>In House documented methods based on current UK Standards for Microbiology Investigations (SMIs):</p> <p>Identification and staining methods using the following manual techniques:</p> <p>Gram stain, Manual biochemical test assays SOP INIS-LP-226-X</p> <p>Using manual slide agglutination technique</p> <p>Enteric C&amp;S SOP INIS-LP-207-X</p> <p>Using BD MGIT MTBc identification card:</p> <p>TB SOP INIS-LP-213-X</p>	<p>CXH (M)</p>



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<p>HUMAN BODY FLUIDS AND TISSUES (cont'd)</p> <p>Blood, Bone marrow, stem cell material, Bone</p> <p>Bronchio-alveolar lavages (BAL) / washings,</p> <p>Pleural effusions / fluid</p> <p>Contact lens and fluid</p> <p>Corneal scrape material</p> <p>CSF , Fluids, Aspirates, antral washouts, drain fluids</p> <p>Lymph node aspirates (including ultra sound guided EBUS)</p> <p>Pus, Sputum, Swabs</p> <p>Prostheses, heart valves</p> <p>Tissue, biopsies, brushes</p> <p>Urine</p>	<p><u>Microbiology examination activities for the purpose of clinical diagnosis</u> (cont'd)</p> <p>Microscopic examination in order to detect and differentiate microorganisms and cellular elements for the purpose of diagnosis</p>	<p>In House documented methods based on current UK Standards for Microbiology Investigations (SMLs):</p> <p>Light microscopy (stained) using Gram stain, Diff-Quick Differential stain and Lactophenol cotton blue, lactofuscin.</p> <p>Microbiology Identification &amp; Staining Methods SOP INIS-LP-226-X</p> <p>Kiestra SOP INIS-LP-260-X</p> <p>CSF SOP INIS-LP-204-X</p> <p>Cross Infection SOP INIS-LP-201-X</p> <p>ENT SOP INIS-LP-270-H</p> <p>Enteric C&amp;S SOP INIS-LP-207-X</p> <p>Faeces C. difficile culture SOP INIS-LP-203-X</p> <p>HVS SOP INIS-LP-245-X</p> <p>GUM Bench SOP INIS-LP-246-X</p> <p>Mycology - Fungal Culture SOP INIS-LP-256-X</p> <p>Superficial Mycoses SOP INIS-LP-232-X</p> <p>H.pylori Culture SOP INIS-LP-209-X</p> <p>Peritoneal Dialysis Fluid SOP INIS-LP-210-X</p> <p>Sterile fluids SOP INIS-LP-211-X</p> <p>Sterility Testing SOP INIS-LP-235-X</p> <p>Respiratory SOP INIS-LP-214-X</p> <p>Tissue and Bone SOP INIS-LP-212-X</p> <p>Wounds &amp; General Set Up Bench SOP INIS-LP-242-X</p> <p>Wounds and General bench reading SOP INIS-LP-241-X</p>	<p>CXH (M)</p>



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Microbiology examination activities for the purpose of clinical diagnosis</u> (cont'd)	In House documented methods based on current UK Standards for Microbiology Investigations (SMI)	CXH (M)
Sputum, Bronchio-alveolar lavages (BAL) Pleural fluid / effusions CSF, Fluids, Pus Gastric washings Lymph node aspirates (including ultra sound guided EBUS), Tissues, biopsies, brushes, skin biopsies, Blood, bone marrow		Immunofluorescent microscopy using Auramine staining and Light microscopy using Ziehl-Neelsen staining:  TB SOP INIS-LP-213-X	
Sputum, Bronchio-alveolar lavages (BAL) / washings, Pleural fluids / effusions Blood, bone marrow CSF, Fluids, Pus Tissues, biopsies	Microscopic examination in order to detect and differentiate microorganisms and cellular elements for the purpose of diagnosis	Immunofluorescent microscopy using Calcoflor and Light Microscopy (unstained)  Fungal Culture SOP INIS-LP-256-X	
Faeces, Sellotape slides, parasitic material	Microscopic examination in order to detect the presence of parasites (ova, cysts, trophozoites, worms)	Manual microscopy (unstained)  Faeces OCP SOP INIS-LP-208-X	
Urine	Microscopic examination in order to detect the presence of Schistosomes.	Manual microscopy (unstained):  Urine SOP INIS-LP-230-X	
Urine	Urine culture and sensitivity testing	MAST UriSystem  MAST Uri@System SOP INIS-LP-270-X	
Faeces	Microscopic examination in order to detect the presence of Cryptosporidium sp.	Immunofluorescent microscopy using auramine staining:  Faeces OCP SOP INIS-LP-208-X	
Faeces	Detection of Helicobacter sp. antigen	Using the Dynex DS2 Automated ELISA System:  Helicobacter Antigen SOP INIS-LP-221-X	





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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Microbiology examination activities for the purpose of clinical diagnosis</u> (cont'd)	In House documented methods based on current Public Health England (PHE) Standards for Microbiology Investigations (SMI):	CXH (M)
Faeces	Detection of GDH and <i>Clostridium difficile</i> toxins A and B	Using rapid membrane enzyme immunoassay: C. Diff Quik Chek Complete C.difficile Rapid SOP INIS-LP-202-X  Using Manual Immunochromatographic lateral flow:	
Serum, CSF	Cryptococcal Antigen	Using IMMY Lateral Flow Assay Cryptococcal Antigen Detection SOP INIS-LP-253-X	
Urine	Pneumococcal Urinary Antigen	Binax NOW Streptococcus pneumonia urinary antigen card: Pneumococcal Urinary Antigen SOP INIS-LP-217-X	
Urine	Legionella Urinary Antigen	Binax NOW Legionella urinary antigen card: Legionella Urinary Antigen SOP INIS-LP-218-X	



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<p>HUMAN BODY FLUIDS AND TISSUES (cont'd)</p> <p>Sputum, Bronchio-alveolar lavages (BAL) / washings, ultra sound guided EBUS)</p> <p>Swabs</p> <p>Cultured Isolates</p>	<p><u>Molecular examination activities for the purpose of clinical diagnosis</u></p> <p>Mycobacteria tuberculosis complex and rifampicin resistance detection</p> <p>MRSA and SA detection to identify mecA, mecC and SCCmec subtype'</p> <p>Detection and differentiation of the blaKPC, blaNDM, blaVIM, blaOXA-48, and blaIMP-1 gene sequences associated with carbapenem-non-susceptibility in Gram-negative bacteria</p>	<p>In house documented procedures based on equipment manuals and standard methods:</p> <p>Real Time PCR using GeneXpert and Ultra-10 kit</p> <p>TB GeneXpert SOP INIS-LP-238-X</p> <p>Cepheid GeneXpert SOP INIS-LP-262-X</p> <p>Real Time PCR using GeneXpert and Nasal (NxG) kit:</p> <p>Cepheid GeneXpert SOP INIS-LP-262-X</p> <p>MRSA GeneXpert SOP INIS-LP-251-X</p> <p>Real Time PCR using Cepheid GeneXpert and Carba-R Assay:</p> <p>Cepheid GeneXpert SOP INIS-LP-262-X</p> <p>Xpert Carba Cepheid Complete INIS-LP-257-X</p>	<p>CXH (M)</p>



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Molecular examination activities for the purpose of clinical diagnosis (cont'd)</u>	In house documented procedures based on equipment manuals and standard methods:	CXH (M)
Faeces	Detection of: <i>Salmonella enterica</i> <i>Shigella spp</i> Enteroinvasive <i>E.coli</i> , <i>Campylobacter jejuni/coli/lari</i> , Shiga toxin producing <i>E.coli</i> (STEC), <i>Cryptosporidium parvum/hominis</i> <i>Giardia lamblia</i>	EntericBio Gastro Panel 2 by Real Time PCR Serosep autosampler and Roche light cyclers 480  SOP INIS-LP-264-X	
Faeces	Detection of <i>Clostridium difficile</i>	Real Time PCR Serosep autosampler and Roche light cyclers 480  SOP INIS-LP-269-X	



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<p>HUMAN BODY FLUIDS AND TISSUES (cont'd)</p> <p>Serum</p>	<p><u>Immunology examination activities for the purpose of clinical diagnosis</u></p> <p><u>Allergy and Immune Serology</u></p> <p>Specific IgE for the following</p> <p>Almond Alternaria Alternata Amoxicillin Ampicillin Apple Aspergillus Avocado Banana Barley Beef Blue Mussel Brazil Nut Carrot Casein</p>	<p>Fluoro Enzyme Immuno Assay (FEIA) by Phadia250 using SOP:</p> <p>INIS-LP-068-X</p>	<p>CXH (I)</p>
	<p>Cladosporium Candida Albicans Cashew Nut Cat Cefaclor Cheese Cheddar Chick Pea Chicken Meat Chilli Pepper Chocolate Cockroach Coconut</p>		



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<p>HUMAN BODY FLUIDS AND TISSUES (cont'd)</p> <p>Serum (cont'd)</p>	<p><u>Immunology examination activities for the purpose of clinical diagnosis</u> (cont'd)</p> <p><u>Allergy and Immune Serology</u> (cont'd)</p> <p>Specific IgE for the following (cont'd)</p> <p>Cod Fish Coffee Corn Cows Milk Crab Cray Fish</p>	<p>In house documented procedures based on equipment manuals and standard methods:</p> <p>Fluoro Enzyme Immuno Assay (FEIA) by Phadia250 using SOP:</p> <p>INIS-LP-068-X</p>	<p>CXH (I)</p>
	<p>Dog Egg White Egg Yolk Garlic Gluten Grape Grass Mix Green Bean House Dust Mite Halibut Hazelnut Honey Honey Bee Venom Horse Kiwi Lamb Latex Lemon Lentil Lobster Lupine Seed</p>		



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HUMAN BODY FLUIDS AND TISSUES (cont'd)  Serum (cont'd)	<u>Immunology examination activities for the purpose of clinical diagnosis</u> (cont'd)  <u>Allergy and Immune Serology</u> (cont'd)  Specific IgE for the following (cont'd)  Macadamia Nut Mackerel Mould Mix Mango Mixed Tree Morphine Mustard Mushroom Oats Omega-5-Gliadin Onion Orange Oyster Pea	In house documented procedures based on equipment manuals and standard methods:  Fluoro Enzyme Immuno Assay (FEIA) by Phadia250 using SOP:  INIS-LP-068-X	CXH (I)
	Peach Peanut Pear Peacn Nut Penicillin G Penicillin V Pine Nut Pistachio Nut Pork Potato Rabbit Epithelium Red Kidney Bean Rice Salmon Sardine Scallop Sesame Seed Shrimp Silver Birch Soya Bean Squid Strawberry Sunflower Seed Suxamethonium		



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<p>HUMAN BODY FLUIDS AND TISSUES (cont'd)</p> <p>Serum (cont'd)</p>	<p><u>Immunology examination activities for the purpose of clinical diagnosis</u> (cont'd)</p> <p><u>Allergy and Immune Serology</u> (cont'd)</p> <p>Specific IgE for the following (cont'd)</p> <p>Tomato Tuna Fish White Bean Walnut Wasp Venom Weed Mix Wheat Yeast</p> <p>Total IgE</p> <p>Tryptase</p>	<p>In house documented procedures based on equipment manuals and standard methods:</p> <p>Fluoro Enzyme Immuno Assay (FEIA) by Phadia250 using SOP:</p> <p>INIS-LP-068-X</p> <p>INIS-LP-068-X</p>	<p>CXH (I)</p>



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Serum	Glomerular Basement Membrane Ab	Fluoro Enzyme Immuno Assay (FEIA) by Phadia250 using SOP:  INIS-LP-062-X	
	ANCA: MPO antibodies	INIS-LP-062-X	
	ANCA: PR3 antibodies	INIS-LP-062-X	
	Anti-Nuclear antibody (ANA) screen (CTD screen)	INIS-LP-062-X	
Serum	Detection of Aspergillus IgG	INIS-LP-068-X	
		Enzyme Linked Immunosorbent Assay (ELISA) DS2 using SOP:	
	Intrinsic Factor IgG antibodies	INIS-LP-118-X	
	PLA2R	INIS-LP-070-X	
	Pneumococcal antibodies	INIS-LP-071-X	
	Tetanus antibodies	INIS-LP-105-X	
		Enzyme Linked Immunosorbent Assay (ELISA) Manual method using SOP:	
	Glutamate Decarboxylase Antibody	INIS-LP-065-X	
	Thyroid stimulating hormone receptor (TSHR) antibodies	INIS-LP-006-X	
	Anti-IA2 IgG	INIS-LP-085-X	
		Automated immunofluorescence using the Inova Quantalyser 3000:	CXH (I)





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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Immunology examination activities for the purpose of clinical diagnosis (cont'd)</u>	In house documented procedures based on equipment manuals and standard methods:	CXH (I)
Serum	dsDNA (Crithidia substrate)	INIS-LP-120-X	
	Endomysium antibodies (IgA)	INIS-LP-120-X	
	Liver autoantibody screen (LKS): Anti-Smooth Muscle antibody (SMA) IgG (LKS screen), Anti Mitochondrial Antibody (LKS Screen), Anti-gastric parietal cells (LKS Screen), Liver/kidney microsomal Ab (LKS Screen)	INIS-LP-120-X	
	Antinuclear antibodies IgG (ANA Hep2 screen)	INIS-LP-120-X	
	Neuronal antibodies	INIS-LP-120-X	
	Anti-neutrophil cytoplasmic antibody (ANCA) (IgG)	INIS-LP-120-X	



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HUMAN BODY FLUIDS	<u>Immunology examination activities for the purposes of clinical diagnosis</u> (cont'd)	Documented In-house Methods and Manufacturer's instructions for analyser with specific reference to:  Indirect Immunofluorescence by manual method using SOP:	CXH (I)
Serum	Adrenal Cortex Antibody	INIS-LP-120-X	
Serum	Ovarian antibodies	INIS-LP-120-X	
Serum	Anti-Nuclear Antibody (ANA) (IgG)	INIS-LP-120-X	
Serum	Liver autoantibody screen (LKS): Anti-Smooth Muscle antibody (SMA) IgG Anti Mitochondrial Antibody (AMA) Anti-gastric parietal cells Liver/kidney microsomal Ab (LKM)  C1-Esterase inhibitor  IgG Subclasses  MPO, PR3 and GBM antibody confirmations  Liver autoantibody confirmation (AMA-M2, 3E (BPO), Sp100, PML, gp210, LKM-1, LC-1, SLA/LP, Ro52)	INIS-LP-120-X          Optilite SOP INIS-LP-117-X   Immunoblot by Euroblot One/manual technique using SOPs:  INIS-LP-016-X (Euroblot 1) INIS-LP-017-X (manual)  INIS-LP-016-X (Euroblot 1) INIS-LP-017-X (manual)	



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HUMAN BODY FLUIDS (cont'd):	<u>Immunology examination activities for the purposes of clinical diagnosis</u> (cont'd)  Myositis immunoblot (Ro52, OJ, EJ, PL-12, PL-7, SRP, Jo-1, PM-Sc1 75, PM-Sc1 100, Ku)	Documented In-house Methods and Manufacturer's instructions for analyser with specific reference to:  INIS-LP-016-X (Euroblot 1) INIS-LP-017-X (manual)	CXH (I)
Serum, CSF	Neuronal autoantibody confirmation (Amphiphysin, CV2, PNMA2(MA2), Ri, Hu, YO)	INIS-LP-017-X	
		Multiplex Flow Immunoassay by Bio-Rad Bioplex 2200 using SOP:	CXH (I)
Serum	IgA, IgG anti-tissue transglutaminase antibodies	INIS-LP-106-X	
Serum	ANTI-dsDNA Quantitative assay	INIS-LP-114-X	
Serum	Anti-Extractable Nuclear Antigens (Ribosomal P, Ro52, Ro60, SS-B/La, Centromere B, Sm, SmRNP, RNP68, RNPA, Scl-70, Jo-1)	INIS-LP-114-X	
Serum	Anti cardiolipin antibody IgG, IgM	INIS-LP-115-X	
Serum	Anti β2 glycoprotein 1 IgG, IgM antibody	INIS-LP-115-X	



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HUMAN BODY FLUIDS (cont'd):	<u>Immunology examination activities for the purposes of clinical diagnosis</u> (cont'd)	Documented In-house Methods and Manufacturer's instructions for analyser with specific reference to:	CXH (I)
	<u>Cellular Assays</u>		
Whole blood	Immunophenotyping of the following markers/antigens to diagnose and monitor primary and secondary immunodeficiency:	Flow Cytometry by Beckman Coulter Navios using SOP:	
Whole blood	Lymphocyte Subsets	INIS-LP-044-X	
	Immunophenotyping of the following markers/antigens to diagnose and monitor primary and secondary immunodeficiency:	Flow Cytometry by Beckman Coulter Navios using SOP:	
	B cell memory panel	INIS-LP-002-X	
	T cell memory panel	INIS-LP-002-X	
	Activated T cells (%)	INIS-LP-003-X	
	T Cell Subsets (CD4/CD8)	INIS-LP-044-X	
		In vitro stimulation cytokine release ELISA, ELISpot by DS2 using SOP:	
	Quantiferon TB Assay	INIS-LP-010-X	
	<u>Immunodeficiency and Complement</u>		
Serum	Alternative Complement Pathway	Enzyme Linked Immunosorbent Assay (ELISA) Manual using SOP: INIS-LP-064-X	
	Complement C1q Antibody	INIS-LP-012-X	
	Total haemolytic complement	INIS-LP-064-X	



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HUMAN BODY FLUIDS (cont'd):	<u>Immunology examination activities for the purposes of clinical diagnosis</u> (cont'd)	Documented In-house Methods and Manufacturer's instructions for analyser with specific reference to:	CXH (I)
	Functional C1 inhibitor	Manual Photometric Analysis using SOP:  INIS-LP-009-X	
	<u>Microbiology &amp; Serology</u>	Manual Latex agglutination test using RHEUMAJET ASO and SOP:	CXH (I)
	Anti-Streptolysin O titre	INIS-LP-021-X	CXH (I)
	Serum	Rapid Plasma Reagin (RPR)  INIS-LP-023-X	
Serum	Detection of <i>Treponema pallidum</i>	Manual TPHA test using the Fortress TPHA kit  INIS-LP-283-X	CXH (I)
Serum	Aspergillus $\beta$ -D-Glucan abtigen detection	Kinetic turbidimetric method using the Fujifilm $\beta$ -Glucan Test on the MT-6500 Toxinometer  INIS-LP-113-X	CXH (I)



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HUMAN BODY FLUIDS (cont'd):	<u>Microbiology and Serology examination activities for the purposes of clinical diagnosis</u> (cont'd):	Documented In-house Methods and Manufacturer's instructions for analyser with specific reference to:	
	Hepatitis E IgG, IgM	Fortress Diagnostics by Enzyme Linked Immunosorbent Assay (ELISA) by DS2:  INIS-LP-084-X	CXH (I)
	Lyme (Borrelia) IgG / IgM	Euroimmun by Enzyme Linked Immunosorbent Assay (ELISA) by DS2:  INIS-LP-098-X	CXH (I)
Serum Bronchoalveolar Lavage	Aspergillus galactomannan antigen detection	Platelia™ Aspergillus EIA using the Dynex DS2  INIS-LP-127-X	CXH (I)
	Hepatitis B Surface Antigen confirmation	Chemiluminescence immunoassay (CLIA) by Diasorin Liaison XL using SOP:  INIS-LP-096-X	CXH (I)
	Hepatitis B Core Total Antibody	INIS-LP-095-X	
	Herpes Simplex virus (HSV) IgG	INIS-LP-102-X	
	Measles Virus IgG, IgM	INIS-LP-101-X	
	Mumps IgG, IgM	INIS-LP-097-X	
	Parvovirus IgG, IgM	INIS-LP-107-X	
	Varicella Zoster Virus (VZV)	INIS-LP-126-X	



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HUMAN BODY FLUIDS (cont'd):	<u>Microbiology and Serology examination activities for the purposes of clinical diagnosis</u> (cont'd):	Documented In-house Methods and Manufacturer's instructions for analyser with specific reference to:	
	HIV1/2 antibody/antigen confirmation	Multiplex Flow Immunoassay by Bio-Rad Bioplex 2200 using HIV Confirmation Bio-Rad Bioplex using SOP:  INIS-LP-094-X	CXH (I)
	HIV Antibody Typing Assay	Immunochromographic technique using Biorad Geenius HIV I/II Confirmatory Assay using SOP:  INIS-LP-077-X	CXH (I)
		Documented In-house Methods and ELITechELITE InGenius™ and HEV ELITE MGB kit Manufacturer's instructions for analyser with specific reference to SOP:	
	Genital swabs Urine	<i>Mycoplasma genitalium</i> detection and macrolide resistance testing	INIS-LP-306-X
Plasma	Detection of Hepatitis E	INIS-LP-309-X	
Plasma	Detection of Parvovirus B19	INIS-LP-309-X	
Plasma	Detection of HHV6	INIS-LP-309-X	



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HUMAN BODY FLUIDS (cont'd):	<u>Microbiology and Serology examination activities for the purposes of clinical diagnosis</u> (cont'd)	Documented In-house Methods and Roche Cobas 6800/8800 Manufacturer's instructions for analyser with specific reference to SOP:	CXH (I)
Plasma	Quantitative CMV viral Load	INIS-LP-082-X	
Plasma Serum	Quantitative Hepatitis C Virus viral load	INIS-LP-082-X	
Plasma	Quantitative Hepatitis B Virus viral load	INIS-LP-082-X	
Plasma	Quantitative HIV-1 viral load	INIS-LP-082-X	
Cervical, vaginal, vulval, throat and rectal swabs Urine	Detection of CT/NG (DNA)	INIS-LP-304-X	
Cervical and vaginal swabs Urine	Detection of <i>Trichomonas vaginalis</i> (DNA)	INIS-LP-104-X	
Cervical and vaginal swabs Urine	Detection of <i>Mycoplasma genitalium</i> (DNA)	INIS-LP-104-X	
Urine Plasma	Detection of BK Virus	INIS-LP-00296-X	
Plasma	Detection of Epstein Barr virus	INIS-LP-00296-X	
Plasma	Detection of Adenovirus	INIS-LP-320-X	
Plasma	Detection of protease inhibitor, reverse transcriptase inhibitor and integrase inhibitor resistance	INIS-LP-121-X	CXH
		Documented in-house methods for Next Generation Sequencing using the Vela Diagnostics NGS assay:	





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HUMAN BODY FLUIDS (cont'd):	<u>Microbiology and Serology examination activities for the purposes of clinical diagnosis (cont'd):</u>		
NPA/BAL/ETA/ swabs	Detection of Influenza A, Influenza B, RSV, Parainfluenza 1, 2, 3, 4, Adenovirus, Rhinovirus, Enterovirus, HMPV, <i>Mycoplasma pneumoniae</i> , <i>Bordetella sp</i> , <i>Bordetella pertussis</i>	Multiplex nested Real time with melt curve analysis PCR using High-Plex 24 system Aus Diagnostics and SOP:  INIS-LP-088-X	CXH (F)
Nose and throat swabs in viral transport media, Sputum	Detection of SARS-CoV-2 (COVID-19) RNA. Specific gene targets ORF1a and ORF8	Using SARS-CoV-2a and 2b High-Plex 24 assay and AusDiagnostic extraction reagents  INIS-LP-088-X  INIS-LP-089-X	CXH (F)



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HUMAN BODY FLUIDS (cont'd):	<u>Microbiology and Serology examination activities for the purposes of clinical diagnosis</u> (cont'd):	Documented In-house Methods and Manufacturer's instructions for analyser with specific reference to:	
Nose and throat swabs in Cobas media	Detection of SARS-CoV-2 (COVID-19) RNA. Specific gene targets ORF1a/b and E gene	Real time PCR with Roche Cobas 6800 using Cobas SARS-CoV-2 kit INIS-LP-082-X	CXH (I)
Nasopharyngeal swab, nasal swab, or nasal wash/ aspirate specimens in eNAT transport medium	Detection of SARS-CoV-2 (COVID-19) gene markers (E, N and RdRp genes)  Influenza A matrix (M), influenza A basic polymerase (PB2), influenza A acidic protein (PA), influenza B matrix (M), influenza B non-structural protein (NS)  RSV A and RSV B	Real-Time PCR using Cepheid Genexpert Xpert Xpress and SARS-CoV-2/Flu/RSV Cepheid four in one test  INIS-LP-125-NWL	CXH (Mol) SMH THH HH
	Detection of SARS-CoV-2 (COVID-19) gene markers (E, N and RdRp genes)	Real-Time PCR using Cepheid Genexpert Xpert Xpress  SARS-CoV-2 INIS-LP-109-NWL	CXH SMH THH HH



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HUMAN BODY FLUIDS (cont'd):	<u>H&amp;I Examination activities for the purposes of clinical diagnosis:</u>	Documented In-house Methods and Manufacturer's instructions for analyser with specific reference to:	
Blood Buccal swabs	DNA Extraction	Semi-automated method using EZ1 DNA Extraction kit INIS-LP-184-H	HH
DNA extracted from blood and buccal swabs	HLA Class I & II Typing	DNA quantification using the Nanodrop, PCR-Sequence Specific Oligo Typing (SSO) Thermal cyclers S1000 or PTC200, or Veriti, Luminex Flexmap 3D:  INIS-LP-157-H	HH
DNA extracted from blood	HLA Class I & II Typing	DNA quantification using the Nanodrop, PCR-Sequence Specific Primer (SSP) Thermal cyclers S1000, PTC200 or Veriti and Quantstudio6 Flex INIS-LP-156-H	HH
Serum	CDC direct crossmatch	Complement Dependent Cytotoxicity (CDC) Inverted fluorescent microscope:  INIS-LP-170-H  BD FACS Lyric flow cytometer:	HH
Serum and cells separated from whole blood	Flow cytometric direct crossmatch	INIS-LP-166-H  INIS-LP-145-H	HH
Serum	HLA Antibody Screen I And II	Luminex Flexmap 3D using OneLambda Labscreen INIS-LP-180-H	HH



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HUMAN BODY FLUIDS (cont'd):	<u>H&amp;I Examination activities for the purposes of clinical diagnosis (cont):</u>	Documented In-house Methods and Manufacturer's instructions for analyser with specific reference to:	HH
DNA extracted from blood	HLA Antibody Characterisation Class I & II	Luminex Flexmap 3D using OneLambda Labscreen Single Antigen and Lifecodes Single Antigen tests: INIS-LP-148-H INIS-LP-143-H	HH
DNA extracted from blood and buccal swabs	HLA B27 HLA B57 High resolution Class I & II	Next Generation Sequencing with iSeqTM100 Sequencing System and DNA quantification using the Qubit 4 Fluorometer with thermal cyclers S1000,PTC200, or Veriti using INIS-LP-149-H	HH
END			